A Guide to the Deposit of Cultures for Patent Purposes at ECACC

ECACC accepts the following as Patent deposits under the Budapest Treaty 1977 and the World Intellectual Property Organisation, Geneva.

- Animal cell lines (including cells of human origin and hybridomas).
- Viruses (up to ACDP category 3 organisms).
- Bacteria.
- DNA (of eukaryotic and prokaryotic origin).

This guide provides you with details of the procedures for making a patent deposit and how to send your deposit to ECACC. ECACC is also able to accept pathogenic yeast, fungi and protozoa as patent deposits. Please enquire for further details.

General Conditions of Accepteance for all Patent Deposits

1. Please complete the appropriate patent deposit Accession Form (link at the bottom of the page) and the Bioharzard Risk Assessment in full for each deposit, and send both forms to ECACC prior to shipment of sample.
2. Once the forms have been receieved, reviewed and accepted by ECACC, will you be issued with a reference number that will need to be quoted in all future correspondence (and on your samples). A purchase order number will need to be faxed to ECACC as soon as possible. **It is only then can ECACC accept your sample.**
3. 12 ampoules are required for deposit. It is essential for quality control purposes that all ampoules are prepared at the same time and are labelled clearly.
4. It is important to ensure that when you deposit any cell lines, the name of the cell line is written in full on the vial. If you have already labelled the vial, then make sure the full detail is written in the section labelled 'Full cell line name'.
5. The depositor agrees to provide a statement regarding the potential hazards represented by the culture (Biohazard Risk Assessment).
6. On receipt of the deposit at ECACC, a provisional Accession Number is allocated and given to the Depositor. This number remains provisional until the successful completion of quality control procedures.
7. The content of at least one ampoule will be examined according to quality control criteria listed below. Cultures must be replaced if consistent low viability or contamination is identified.
8. If any problems arise, the Depositor will be informed immediately, and a further course of action discussed and agreed with the Depositor.
9. Following successful completion of quality control procedures, ECACC will confirm the Accession Number, and issue a receipt, Certificate of Viability and Certificate of Deposition.
10. The depositor agrees to pay the statutory fee - an invoice will be sent after deposition formalities are complete.
11. On acceptance, ECACC agree to hold the deposit under the terms and conditions of the Budapest Treaty, 1977.
12. Deposits are held on condition that they can be preserved without significant change or loss of properties during long term storage.
13. Depositors are requested to supply a sufficient quantity of any special growth factors which may be required during quality control procedures for any deposit.
14. ECACC reserves the right to refuse deposits which represent unacceptable hazards or unacceptable technical difficulties.

Individual Requirements for Each Category of Organism being Deposited for Patent Purposes

Animal Cells
(Including Immunoclones/Hybridomas)

1. Each ampoule must contain at least 4 x 10^6 cells/ampoule with good viability on resuscitation and be free of microbial contaminants (mycoplasma, bacteria and fungi).
2. Quality control procedures include assessment of cell viability and numbers and examination for the presence or absence of microscopic bacteria and fungi.
3. The quality control procedures usually take 5 to 7 weeks to complete.

Viruses

1. Viruses up to and including ACDP Hazard Group 3 pathogens may be accepted by ECACC as deposits.
2. The virus deposit must be capable of being assayed *in vitro* .
3. Virus concentrations are obviously dependent on the strain, but ECACC advises that the best possible stocks be provided as deposits. ECACC may reject virus stocks deposited as patent deposits if the virus titre is considered unacceptably low. The virus stocks must be free of microbial contaminants (mycoplasma, bacteria, fungi).

4. Quality control procedures include assessment of virus titre (not necessarily assessment of viral identity) and microscopic examination for the presence or absence of bacteria and fungi.
5. The quality control procedures do not usually take longer than 10 weeks to complete.
6. The Budapest Treaty fees quoted for virus deposits refer to virus strains capable of being assayed in cell culture, ie by cytopathic effect. However, an increasing number of strains received by ECACC require alternative assay systems. If there is significant extra cost in materials and staff time, this will be passed on to the Depositor. Assay systems and costings will be fully discussed with the Depositors before implementation.
7. If host cells required for virus assay are not available from culture collections, the Depositor is requested to submit these along with the virus deposit.

Bacteria

1. Deposits are accepted in the form of frozen cultures. Frozen cultures must contain a culturable quantity of organisms. Growing cultures can be received on agar and frozen ampoules produced by ECACC by special arrangement.
2. ECACC will examine at least one ampoule for viability and purity of culture.
3. A minimum of 4 weeks should be allowed for completion of quality control tests.

Recombinant DNA

1. Deposits are accepted in the form of frozen ampoules of host organisms containing plasmid or phage, or naked plasmid or phage DNA. Growing cultures can be received on agar and frozen ampoules produced by ECACC by special arrangement.
2. For viable frozen cultures a 'culturable' quantity of organisms (ie sufficient organisms must be present in each ampoule to yield a representative culture) must be deposited, cryopreserved in an appropriate cryoprotectant.
   or
   Naked DNA must be deposited frozen in an appropriate solution eg 10mM Tris, 1mM EDTA (pH7.5), in quantities suitable for electrophoretic analysis.
3. ECACC agrees to examine at least one ampoule for viability (host/vector cultures only) and integrity of recombinant DNA (all deposits). The Depositor must provide sufficient information to carry out this quality control. All deposits will be examined for the presence/absence of microbial contamination (bacteria, fungi).
4. A minimum of 2 weeks should be allowed for completion of quality control tests.

Please contact ECACC before sending samples.

Shipping Instructions - for all types of deposits

1. Please inform ECACC at least 48 hours prior to despatch. If the deposit is a GMO 2 category then do not ship until ECACC has done a risk assessment to allow time for the GMO committee to give approval for it to be deposited within ECACC. This may take up to one month to investigate. Once approved ECACC will then contact you, the customer, giving approval (or not) to ship.
2. Include the: - Estimated time of arrival and date Flight details (Airway bill No. if known).
3. Complete the required accession form: It is essential for ECACC to receive copies of ACCESSION FORMS and BIOHAZARD RISK ASSESSMENTS in advance of deposits particularly to allow time for preparation of unusual media requirements and GMO assessments.
4. Send shipments as early in the week as possible to allow for customs delays. Address the shipment to the Deposit Co-ordinator and send vials by door to door courier.
5. **Frozen Shipments** must be sent in a polystyrene insulated container with walls at least 6cm thick containing at least 4kg of dry ice (solid CO_2). The code 'UN 1845' for dry ice must appear on the outside of the box.
6. There are no import restrictions for non-infectious material into the UK, but to avoid delays at customs attach three copies of a commercial invoice stating a nominal value for frozen vials of 10 US Dollars and the statement 'Non-infectious to Humans'.
7. Label the outside of the container as follows:- DRY ICE - KEEP FROZEN
   (State weight of dry ice)
   BIOLOGICALS FOR MEDICAL RESEARCH
   FRAGILE
   Depositors name, address and contact number.
8. **Growing Cultures** can be sent in 25cm^2 flasks, sealed and packed with sufficient absorbent material to hold total volume of culture media, should leakage occur and to provide insulation against temperature changes. These should then be placed in a crush proof container not just a jiffy bag.
9. Label the outside of the package as follows:-
   PERISHABLE BIOLOGICAL MATERIAL FOR MEDICAL RESEARCH
   DO NOT REFRIGERATE
   INCUBATE AT APPROPRIATE TEMPERATURE
   Depositors name, address and contact number

BIOHAZARDOUS AGENTS

Should you wish to send cells or organisms which fall within the ACDP3 definition of pathogens, additional requirements must be met for shipment.

1. FROZEN MATERIAL
   Labelled frozen material must be placed in a sealed primary container. Use a separate container for each cell or organism type. Absorbent material sufficient to hold the full volume of liquid must be placed around the container(s). These should be placed in a screw capped metal container with waterproof tape which has a 'Biohazard' (symbol), 'Aetiological Agents/Biomedical Material'.

   The metal container must then be fixed inside a polystyrene shipping container so that it will not move after dry-ice is added. The shipping container must be labelled as in paragraph 7 above plus the additional labels:-

   a. Biohazard sign
   b. Description of the agent and volume
   c. Infectious substances affecting humans (if applicable)

2. NON-FROZEN MATERIAL
   Labelled non-frozen material must be sealed in a plastic bag with enough absorbent material to hold the full volume of culture media. This should then be placed in a screw capped metal container and sealed with waterproof tape. The container should be surrounded by shock absorbing material and placed in a rigid shipping container. This must be labelled with:-

   a. Biohazard sign.
   b. Description of the agent and volume.
   c. Infectious substances affecting humans (if applicable)..
   d. Perishable Biologicals for Medical Research.
   e. Depositors name, address and contact number.

3. Please note that deposits into the EC which are, or contain, animal pathogens require an import licence. Please allow 8 weeks for this process, and submit information requested by ECACC for licence applications as quickly as possible.

ecacc
European Collection of Cell Cultures

Related Information

Patent Deposit Accession Form - Cell Culture / Hybridoma

Patent Deposit Accession Form - Virus

Patent Deposit Accession Form - Recombinant DNA

Patent Deposit Accession Form - Bacteria